

(b) recovering the protein.

C2 37. (Once Amended) An isolated protein comprising an amino acid sequence 90% or more identical to amino acid residues 2 to 541 of SEQ ID NO:2, wherein said protein exhibits HLTDG74 biological activity.

C3 44. (Once Amended) An isolated protein comprising an amino acid sequence 90% or more identical to the amino acid sequence of the full-length polypeptide excluding the amino-terminal methionine, which amino acid sequence is encoded by the cDNA contained in ATCC Deposit No. 97186, wherein said protein exhibits HLTDG74 biological activity.

C4 2276 (Once Amended) A protein produced by a method comprising:
(a) culturing a host cell comprising a heterologous nucleic acid molecule 16
encoding the protein of claim 16 under conditions suitable to produce the protein of claim 70;
and
(b) recovering the protein.

Traverse and Remarks

I. Information Disclosure Statement

The Examiner has alleged that references C7-C9, cited on the Information Disclosure Statement submitted January 27, 2000 could not be considered "as no copies could be found of those sequences". For the Examiner's convenience, Applicants herein submit copies of GenBank and Genseq Records for references C7-C9. C7 corresponds to GenBank Accession No. M74445, C8 corresponds to GenSeq Accession No. R92276, and C9 corresponds to GenSeq Accession No. R92278. See, IDS, Page 3, Form PTO-1449, submitted Jan. 27, 2000.

II. Restriction Requirement

Applicants acknowledge notification that the restriction requirement among Groups I-IX has been made final by the Examiner. *See*, Paper No. 12, page 2, last full paragraph through last line. Applicants reserve the right to file, without prejudice, one or more divisional applications directed to the subject matter of claim Groups I and III-IX.

III. Objections and Rejections under 35 U.S.C. §112

A. Claims 51-69

The Examiner rejected claims 51-69 under 35 U.S.C. §112, first paragraph, as allegedly containing "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *See*, Paper No. 12, page 3, first and second paragraphs. (Claims 51-69 are directed to fragments of the protein disclosed in SEQ ID NO:2.)

Applicants respectfully disagree and traverse.

In the Applicants' response of September 1, 2000 to the restriction requirement mailed Mar. 15, 2000, Applicants submitted a tabular representation of the data originally disclosed in Figure 2 of the present application and also in utility application Serial No. 08/468,011 (now Figures 2A-2B in issued U.S. Patent No. 6,030,804) to which this application claims benefit of priority under 35 U.S.C. § 120. This tabular representation merely presents the very same analysis disclosed in Figure 2 of the present application and Figures 2A-2B of the issued patent. Hence, the graphic depiction of polypeptide features shown in original Figure 2 is merely an alternative display of the exact same polypeptide features represented in numerical form by the tabular representation of data previously submitted. In other words, original Figure 2 and the tabular representation of data were both created using the default parameters of a bioinformatics computer program (see Jameson, B.A., and Wolf, H., *Comput. Appl. Biosci.* 4(1):181-6 (1988)) based on the algorithms identified in Figure 2 in the application as originally filed. The difference between the disclosure in Figure 2 and the tabular representation of data is merely one of display. Figure 2 shows the analysis in a graphic format, the tabular representation of data shows the analysis in a numerical format. Moreover, the polypeptide analysis algorithms used to generate Figure 2 are also well-known and readily available to those of ordinary skill in the art. Applicants, therefore, submit that the specification clearly conveys to one skilled in the art that

the Applicants were in possession of the specific HLT DG74 polypeptide fragments disclosed in Figure 2 and the polynucleotide sequences there encoding.

Applicants respectfully remind the Examiner that the specification need not provide written description support in exactly the same words as are used in the claims. In fact, the Federal Circuit has held that it is sufficient that the description conveys to one skilled in the art that Applicants had possession of the invention. For example, see *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984):

[i]t is not necessary that the claimed subject matter be described identically, but the disclosure originally filed must convey to those skilled in the art that applicant has invented the subject matter later claimed.

Moreover, the Federal Circuit has recently affirmed this view by holding "[i]f lack of literal support alone were enough to support a rejection under § 112, then the statement of *In re Lukach* "...that 'the invention claimed does not have to be described *in ipsi verbis* in order to satisfy the description requirement of § 112,' is empty verbiage." See *Union Oil Co. of California v. Atlantic Richfield Co. (Unocal)*, 208 F.3d 989, 1000 (2000). Thus, there is no requirement that the claimed invention be described *verbatim* in the specification of either the present application or in the issued patent to which the present application claims priority.

Accordingly, Figure 2 of the present application, and the figure legend thereto (see page 6 of the specification) teaches that the figure represents structural analyses of the HLT DG74 polypeptide. The figure legend indicates that:

Figure 2 is an illustration of the secondary structural features of the G-protein PTH receptor. The first 7 illustrations set forth the regions of the amino acid sequence which are alpha helices, beta sheets, turn regions or coiled regions. The boxed areas are the areas which correspond to the region indicated.... The antigenic index corresponds to the hydrophilicity plot, since antigenic areas are areas outside the lipid bilayer membrane and are capable of binding antibodies. The surface probability plot further corresponds to the antigenic index and the hydrophilicity plot.

Therefore, the graphic depiction of the HLT DG74 polypeptide sequence and the corresponding description of said depiction clearly describe specific fragments of the HLT DG74 protein.

Moreover, in *Unocal*, the Federal Circuit held that the person of ordinary skill in the art, reading the specification as a whole, would have been able to derive the claimed ranges from separate pieces of disclosure, even though the particular ranges were not explicitly described.

One of ordinary skill in the art at the time the present application was filed would have understood and been able to derive from these and other teachings in the specification that the information provided in Figure 2 suggested fragments of interest of the HLTDG74 protein in the present invention. Applicants respectfully point out that the ordinary skill level in the art is very high, in fact, the skilled artisan often has attained the Ph.D. degree and has pursued postdoctoral studies. Thus, Applicants contend that it is not a large step indeed for one of ordinary skill in the art to combine drawings that detail predicted structural analyses of the molecules of the present invention with detailed teachings regarding the size and exemplary types of fragments to result in the generation of a particular predicted structural feature of a molecule of the invention as a fragment.

Therefore, Applicants assert, contrary to the Examiner's contention that "[t]here is no conception in the specification as originally filed of the specific fragments which applicants now seek to claim", that one of ordinary skill in the art, at the time the present application was filed, would certainly have viewed the specification as teaching specific fragments, such as, for example, those recited in the claims. Accordingly, Applicants respectfully request that the Examiner's rejection of claims 51-69 for allegedly failing to provide adequate support under 35 U.S.C. § 112 be reconsidered and withdrawn.

B. Claims 29-36 and 44-55

The Examiner rejected claims 29-36 and 44-55 under 35 U.S.C. §112, first paragraph, as allegedly containing "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." *See*, Paper No. 12, page 3, last full paragraph. More specifically, the Examiner contends, "[t]he enablement of claims(s) 29-36 and 44-50 requires availability of the specific sequences as contained in the deposited plasmid claimed therein." The Examiner further alleges, "Applicant is advised that the Patent Office accepts Budapest approved deposits, as long as assurance is provided that the deposited material will be made irrevocably available with no restrictions upon issuance of a patent." *See*, Paper No. 12, page 4, first full paragraph.

Applicants respectfully disagree. However, solely in the interest of advancing prosecution, Applicants provide the following statement by an attorney or agent of record over his signature:

Applicants' agent of record hereby declares that ATCC Deposit Nos. 97859 and 97858 have been made under the terms of the Budapest Treaty; that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent from the present application; and that the deposits will be replaced if viable samples cannot be dispensed by the depository.

Applicants, therefore, submit that the rejection of claims 29-36 and 44-55 under 35 U.S.C. §112, first paragraph, has been obviated and respectfully request that the rejection be withdrawn.

C. Claims 37-50

The Examiner rejected claims 37-50 under 35 U.S.C. §112, first paragraph, allegedly because:

[t]he specification, while being enabling for a protein having at least 90% identity to either SEQ ID NO: 2 or the protein encoded by the deposited plasmid (once the deposit has been perfected, see above), which protein either retains activity as a PTH receptor or binding protein or alternatively does not include novel epitopes not found in the protein of SEQ ID NO: 2 or that encoded by the deposited plasmid, does not reasonably provide enablement for proteins which do not retain the binding function of the disclosed protein and which include epitopes not native to the disclosed protein.

See, Paper No. 12, page 4, second full paragraph. Moreover, the Examiner further alleges, "[w]hile enablement would reasonably be found to be commensurate in scope with species 90% identical to SEQ ID NO: 2 and which retain PTH receptor function, the specification does not teach how to use those species which do not retain that function..." See, Paper No. 12, page 4, last sentence of last paragraph.

In accord with the Examiner's suggestion, and solely in the interest of facilitating prosecution, Applicants have herein amended independent claims 37 and 44 to claim 90% or more identical polypeptides "with HLTDG74 biological activity." Applicants, therefore, submit that the rejection of independent claims 37 and 44, as well as corresponding dependent claims

38-43 and 45-50, under 35 U.S.C. §112, first paragraph, has been obviated. Applicants respectfully request the rejection of claims 37-50 be withdrawn.

D. Claims 28 and 76

The Examiner rejected claims 28 and 76 under 35 U.S.C. §112, second paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." *See*, Paper No. 12, page 5, last sentence of last paragraph. Moreover, the Examiner suggested that an amendment to recite "that the host cell comprises a heterologous nucleic acid encoding the protein of claim 21 (or 70, as appropriate) would be remedial". *See*, Paper No. 12, pages 5, last sentence to first line of page 6.

Solely in the interest of facilitating prosecution, Applicants have herein amended claim 28 and claim 76 in accord with the Examiners suggestion. No new matter has been added by these amendments. Applicants, therefore, submit that the rejection of claims 28 and 76 under 35 U.S.C. §112, second paragraph, has been obviated and respectfully request that the rejection be withdrawn.

IV. Prior Art

Applicants acknowledge the Examiner's finding that the claims are free of prior art. Applicants also acknowledge and appreciate the Examiner's allowance of claims 21-27 and 70-75. Applicants also wish to thank the Examiner for her thoughtful consideration of this application.

Conclusion

In view of the foregoing remarks, applicants believe that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application.